

### AMENDMENTS

Claims 1, 3, and 8-17 are pending.

Claims 1 and 3 have been amended.

Claims 2 and 4-7 have been cancelled.

Claims 10-17 have been added.

Support for the amendments is found in the claims and specification (e.g., page 7, ln. 9-22; pages 5-6; page 9; page 10; page 11; page 12; and page 15), as originally filed. Claims 1 and 13 comprise the limitations of claim 7. Additional support for claims 12 and 17 can be found in Table C1 to C3 of Examples C1-C9, wherein the compositions do not comprise calcium ion.

### REMARKS AND REQUEST FOR RECONSIDERATION

The advantageous effect of the claimed oral preparation is that a small amount of calcium phosphate that is present in a small gap between enamel rods of the teeth is turned into fluoride-containing fine particles to form a light scattering layer inside enamel which causes an irregular reflection in response to an incident light radiated from the outside. See pages 1-3 of the present specification. Normally, internal discoloration of the teeth is apparent through transparent enamel of the teeth; however, this light scattering layer which looks white and opaque can shield the yellowish color of the teeth and give the teeth a white appearance, therefore. *Id.* The factors that form the light scattering layer include the components (A), (B) and (C), and a specified pH condition, e.g., see page 10 of the present specification. As shown in the Examples and Comparative Examples of Example B series and Example C series of the present specification, the light scattering layer is not formed when any of the components (A), (B) and (C) is not contained. As the factor for forming the light scattering layer, it is important that the oral preparation contains no calcium. This fact has

been proved by the comparison between Comparative Examples C1 to C3 and Examples C1 to C9 shown in Tables C1 to C3 of the present specification.

Claims 1-4 are rejected as anticipated by Yamagishi and Murakami (one of the inventors of the above-identified application), JP 2002-037721 (Kao Corp.) ("JP '721"). The rejection is traversed because JP '721 does not describe or suggest an oral composition comprising potassium ion which is not contained in a potassium fluoride compound, and the claimed amount of the potassium ion.

JP '721 describes an oral composition for whitening teeth comprising 0.02-0.7 wt.% of a fluorine ion supplying compound, 0.1-5 mol/kg of an acidic compound, and 5-90 wt.% of water. ¶¶ [0006]-[0007]. The fluorine ion supplying compound can be potassium fluoride, potassium monofluorophosphate, sodium fluoride, etc. ¶ [0008].

The present specification describes that the oral preparation of JP '721 forms a layer of calcium fluoride on a surface of the teeth to provide whiteness and gloss (pages 2-3, the bridging paragraph).

Thus, the oral preparation of JP '721 does not comprise potassium ion except when a fluorine ion supplying compound is potassium fluoride or potassium monofluorophosphate, not to mention 0.03-0.5 mol/kg of the potassium ion. Also, JP '721 forms a layer of calcium fluoride on the surface of the teeth and is not known to be capable of forming a light scattering layer inside enamel of the teeth when the oral preparation is applied to teeth.

Thus, JP '721 does not anticipate the claimed oral preparation.

Applicants request that the rejection be withdrawn.

Claims 1-4 are rejected under 35 U.S.C. 102(b) over Ochiai et al., US 4,363,794 and under 35 U.S.C. 102(e) Majeti et al., US 2003/0124065. The rejections are traversed because:

(a) Ochiai et al. does not describe or suggest an oral composition comprising potassium ion which is not contained in a potassium fluoride compound, and the claimed amount of the potassium ion;

(b) the Ochiai et al. composition is not known to be capable of forming a light scattering layer inside enamel of the teeth;

(c) Majeti et al. do not describe the claimed amount of the potassium ion; and

(d) the Majeti et al. composition is not known to be capable of forming a light scattering layer inside enamel of the teeth.

**Ochiai et al.** describe an oral composition comprising a stannous salt (e.g., stannous fluoride), a water-soluble fluoride salt (including potassium fluoride or potassium monofluorophosphate), and an acid (col. 4 and the examples).

Ochiai et al. do not describe an oral composition comprising potassium ion except when a fluorine ion supplying compound is potassium fluoride or potassium monofluorophosphate, not to mention the claimed amount of the potassium ion.

Moreover, the Ochiai et al. composition etches the tooth surface and then forms a film on the surface. Col. 4, ln. 66 to col. 5, ln. 25. Thus, the Ochiai et al. composition is not known to be capable of forming a light scattering layer inside enamel of the teeth. This property is not inherent because the Ochiai et al. composition is different (i.e., does not comprise the potassium ion which is not potassium fluoride or potassium monofluorophosphate). Ochiai to describe using 3.7 to 7 mol of fluoride ion (col. 4, ln. 60-62). If potassium fluoride is contained in an amount of as much as 3.2 mol in terms of the fluoride ion, the potassium amount is excessive and exceeds the claimed range.

Thus, Ochiai et al. do not anticipate the claimed oral preparation.

**Majeti et al.** describe an oral cleaning, whitening, and stain removing composition comprising a PVP/AC polymer and may also comprise 0.0025-5.0 wt.% of a fluoride source

(including potassium fluoride), and, optionally, 0.1-2.5 wt.% of an acid or a salt (e.g., ¶¶ [0035], [0081]-[0082], and [0088]). Majeti et al. further describe that teeth whitening additives may be used in the composition with, e.g., potassium chloride or potassium persulfate, ¶ [0090].

Majeti et al. do not describe an oral composition comprising the claimed amount of potassium ion in combination with fluorine atom and an acid and its salt. In fact, Majeti et al. do not describe a single example comprising the claimed components.

In addition, the Majeti et al. composition forms a film and removes external stains from the surface of the teeth formed by coffee, tea, etc. ¶ [0035]. Thus, the Majeti et al. composition is not known to be capable of forming a light scattering layer inside enamel of the teeth.

Moreover, Majeti et al. do not describe using malic acid and/or tartaric acid as in claim 3. The buffer system which is composed of the malic acid and/or tartaric acid and the salts thereof have a strong buffering capability and thus can sufficiently form fluoride-containing fine particles even in a low acid concentration and provide a markedly superior effect in whitening of the teeth (see US2006/0099153 (published application), paragraphs [0036] and [0037]). It is possible to suppress the sour taste by using the buffer system (see US2006/0099153, paragraphs [0036] and [0038]).

Thus, Majeti et al. do not anticipate the claimed oral preparation.

Applicants request that the anticipating rejections over Ochiai et al. and Majeti et al. be withdrawn.

Claims 6-7 are rejected under 35 U.S.C. 103(a) over Majeti et al. Claims 5-7 are rejected as obvious over each (a) Ochiai et al. and Majeti et al., and (b) JP '721 and Majeti et

al. Although claims 4-7 have been cancelled, Applicants will address these rejections because the limitations of claim 7 have been introduced in claims 1 and 13.

The rejections are traversed because the combinations of the references do not describe or suggest the claimed amount of potassium ion and the combined oral compositions are not known to be capable of forming a light scattering layer inside enamel of the teeth.

The disclosures of Ochiai et al., Majeti et al., and JP '721 are described above. The examiner is of the opinion that optimizing the content of potassium ion of Majeti et al. would have been obvious. Applicants respectfully disagree.

Majeti et al. describe an oral composition for surface whitening, e.g., rinsing, brushing, or polishing teeth with the composition. ¶¶ [0002], and the Examples. The Majeti et al. may or may not comprise additional whitening additives and chelating agents. ¶¶ [0081] and [0090].

In the claimed oral composition, when potassium ion is not included, the light scattering effect is inferior. *See* Examples B1-B9 and Comparative Examples B1-B9 in Tables B1-B3 and pages 28-35 of the present specification.

“In the toothpastes of Examples B1 to B3, the addition of potassium ion allowed a reduced amount of the organic and/or inorganic acid to fulfill an effective amount thereof, and therefore these toothpastes exhibited a formation of the light scattering layer inside the enamel of the teeth, and excellent whitening effect. Further, each taste of them was also good because amount of the acid was small.

In contrast, because the toothpaste of Comparative Example B1 contained only small amount of the organic acid and/or inorganic acid, the toothpaste provided a good taste but did not exhibit a formation of the light scattering layer nor whitening effect. Also, because the toothpastes of Comparative Examples B2 and B3 contained too much amount of the organic acid and/or inorganic acid, the toothpastes exhibited no formation of a light scattering layer and also provided rather lower whitening effect, and a poor taste.

In the liquid dentifrices of Examples B4 to B6, the addition of potassium ion allowed a reduced amount of the organic and/or inorganic acid to fulfill an effective amount thereof, and therefore these liquid

dentifrices exhibited a formation of the light scattering layer inside the enamel of the teeth, and excellent whitening effect. Further, each taste of them was also good because amount of the acid was small.

In contrast, because the liquid dentifrice of Comparative Example B4 contained only small amount of the organic acid and/or inorganic acid, the liquid dentifrice provided a good taste but did not exhibit a formation of the light scattering layer nor whitening effect. Also, because the liquid dentifrices of Comparative Examples B5 and B6 contained too much amount of the organic acid and/or inorganic acid, the liquid dentifrices provided a poor taste, no formation of a light scattering layer and rather lower whitening effect.

In the mouthwashes of Examples B7 to B9, the addition of potassium ion allowed a reduced amount of the organic and/or inorganic acid to fulfill an effective amount thereof, and therefore these mouthwashes exhibited a formation of the light scattering layer inside the enamel of the teeth, and excellent whitening effect. Further, taste was also good because amount of the acid was small.

In contrast, because the mouthwash of Comparative Example B7 contained only small amount of the organic acid and/or inorganic acid, the mouthwash provided a good taste but no whitening effect. Also, because the mouthwashes of Comparative Examples B8 and B9 contained too much amount of the organic acid and/or inorganic acid, the mouthwashes provided bad taste, no formation of a light scattering layer and rather lower whitening effect.”

Page 33, ln. 13 to page 35, ln. 2 of the present specification.

Similar results are obtained in Examples C1-C3 on pages 36-40 of the present specification with respect to the addition of potassium ion.

Thus, the claimed composition comprising the components (A), (B), (C), and (D) provides an advantageous result compared to the compositions that do not comprise potassium ion and the claimed amount of the components.

Thus, the claimed oral preparation is not obvious over the cited references.

Applicants request that the obviousness rejections be withdrawn.

A Notice of Allowance for all pending claims is requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, L.L.P.  
Norman F. Oblon



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Richard L. Chinn, Ph.D.  
Attorney of Record  
Registration No. 34,305

Marina I. Miller, Ph.D.  
Registration No. 59,091

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 07/09)